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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,514	01/30/2004	Anthony Bernard Schryvers	028722-376	8013
21839	7590	07/06/2006		EXAMINER
BUCHANAN INGERSOLL PC				BASKAR, PADMAVATHI
POST OFFICE BOX 1404				
ALEXANDRIA, VA 22313-1404			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 07/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/769,514	SCHRYVERS, ANTHONY BERNARD
	Examiner Padmavathi v. Baskar	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 April 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-27 is/are pending in the application.
 - 4a) Of the above claim(s) 5 and 15-27 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4 and 6-14 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Amendment

1. Applicant's amendment filed on 4/12/06 is acknowledged.

Election/Restriction

2. Applicant's election of Group 1, claims 2-24 drawn to a molecule binding to transferrin polypeptide SEQ.ID.NO: 17, vaccine composition is acknowledged.

The traversal is on the ground(s) that searching 10 additional sequences would not be an undue burden "

This is not found persuasive because there is nothing on the record that these inventions are not patentably distinct. As to the question of burden of search is merely one indication of the burdensome nature of the search involved. While search is not unduly burden on the Examiner, each invention is examined based on its merits and enablement. It would not constitute an undue burden although these sequences are identified by the examiner as patentably distinct.

Status of claims

3. Claims 1-27 are pending.

Claims 1-4, 6-14, SEQ.ID.NO: 17 have been elected for prosecution in this application and are under examination.

Claim 5 is withdrawn from elected invention as claims are drawn to SEQ.ID.NO: 1-14, non-elected subject matter.

Claims 15-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group of inventions and there being no allowable generic or linking claim.

Priority

4. This application is 10/769,514 claims priority from Provisional Application 60/444,113, 01/31/2003.

Information Disclosure Statement

5. No Information Disclosure Statement, Form 1449 has been filed in this application.

Claim objections

6. Applicant elected peptide SEQ.ID.NO: 17, therefore, applicant is requested to amend the claims to read on elected peptide SEQ.ID.NO: 17.

Claim Rejections - 35 USC 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor or carrying.

8. Claims 8-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Instant claims are evaluated for enablement using Wands analysis. Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed.Circ.1988) as follows:

(1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence

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of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

Enablement of a “vaccine composition” is considered to rest on a teaching of *in vivo* administration for purposes consistent with the intended use disclosed in the specification. The disclosed intended use for the claimed vaccine is for the treatment of disease caused by gram negative bacteria. Thus, the nature of the invention is a vaccine capable of eliciting antibodies that recognize plurality of different transferrin binding proteins, said proteins from *Neisseria* spp., *Haemophilus* spp., *Moraxella* spp., *Mannheimia* (*Pasteurella*) spp., *Actinobacillus* spp., and *Staphylococcus* spp, said composition used in the treatment or prevention of infection. In addition, the instant specification does not teach how to use the composition, without undue experimentation, for the prevention, treatment, or cure of a disease in the animal to which the substance is administered.

The nature of the disclosed invention is vaccine comprising an isolated polypeptide SEQ.ID.NO: 17. This polypeptide is for inhibiting or preventing gram-negative bacteria *N.meningitidis* *Haemophilus* spp., *Moraxella* requiring *in vivo* enablement for intended use of this polypeptide. The specification discloses that the polypeptide, TbpB of the instant claims has been obtained from *M.catarrhalis* strain 4223. The intended use of this transferring binding protein is “vaccine” composition “useful for preventing meningococcal infections.” The specification, however, provides no working examples demonstrating (i.e., guidance) enablement for any *in vivo* uses of the claimed polypeptide. The induction of protective immune response (i.e., bactericidal and protective antibody response) to a meningococcal polypeptide or polysaccharide is complex and unpredictable against all meningococcal serogroups, serotypes and serosubtypes (see abstract of *Biotecnologia Aplicada* 1996, Vol 13, 1-7). However, it is unclear whether target antigen, an isolated polypeptide SEQ.ID.NO: 17 has been shown to elicit

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a protective antibody response. Furthermore, it is unclear whether the claimed polypeptide elicits effective (i.e., protective) antibodies that are bactericidal (in vitro) and protective (in vivo) against any serogroup. Thus, an isolated polypeptide, SEQ.ID.NO: 17 as a vaccine composition in the treatment or prevention of meningococcal infections must be considered highly unpredictable, requiring a specific demonstration of efficacy of the polypeptide in any animal model. Absent such demonstration, the invention would require undue experimentation to practice as claimed.

Claim Rejections - 35 USC 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-4, and 6-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Myers et al US-PAT-NO: 6090576.

Claims are drawn to an isolated molecule capable of (a) binding to a region of transferrin that is recognized by a bacterial transferrin binding protein; and (b) eliciting an antibody to said bacterial transferrin binding protein, wherein the molecule is an antibody, wherein the molecule is a recombinant protein or peptide, wherein the transferrin is human transferrin, said peptide comprising the sequence of SEQ ID NO: 17. Claims are also drawn to vaccine comprising said peptide.

Myers et al U.S.PAT: 6,090,576 disclose a molecule, transferrin binding protein from *M.catarrhalis* strain 4223 in SEQ.ID.NO: 10. This recombinant protein comprises the disclosed peptide SEQ.ID.NO: 17 and is 100% identical to the claimed protein from position 80-93-113

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(see the sequence alignment). The art discloses monoclonal antibodies or mono-specific antisera (antibodies) raised against the transferrin receptor protein produced (column 2, lines 20-40) and are useful for the diagnosis of infection by Moraxella, the specific detection of Moraxella (in, for example, in vitro and in vivo assays) and for the treatment of diseases caused by Moraxella. The art discloses said protein specifically binds to human transferrin (column 4, line 44) and is structurally identical to the claimed peptide, SEQ.ID.NO: 17 and therefore, antibodies to this peptide bind to plurality of transferrin binding proteins. In the absence of evidence to the contrary the claimed transferring binding peptide and the disclosed transferrin binding peptide appears are same as both contain 100% identical peptide. The art discloses vaccine composition comprising said lactoferrin-binding protein against gram-negative bacteria including *M.catarrhalis*, *N.meningitidis* and *Haemophilus influenzae* (see column 8, lines 25-60).

Applicant's use of the open-ended term "comprising" in claims fails to include unrecited steps or ingredients and leaves the claims open for inclusion of unspecified ingredients, even in major amounts). See *In re Horvitz*, 168 F 2d 522, 78 U.S.P.Q. 79 (C.C.P.A. 1948) and *Ex parte Davis et al.*, 80 U.S.P.Q. 448 (PTO d. App. 1948). It is acknowledged that weight is given to every term in vaccine claims. This is why the instant claims drawn to vaccine are scrutinized differently from a composition claim under 112, first paragraph. However, under prior art rejections, the term vaccine must be weighed with the structural limitations of the claim. If the compositions merely comprise a known composition, the term carries little weight absent evidence of structural difference. Of course, the existence of an unobvious structural difference would define over the prior art. Here, the prior art teaches the same compound, peptide as claimed. *In re Thorpe*, 227 U.S.P.Q. 964, 966 (Fed. Cir. 1985). *In re Marosi*, 218 U.S.P.Q. 289, 293-293 (C.A.F.C. 1983). *In re Best*, 195 U.S.P.Q. 430, 433 (C.C.P.A. 1977). *In re Brown*, 173 U.S.P.Q. 685, 688 (C.C.P.A. 1972).

11. Claims 1-4, and 6-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Loosmore et al 1999 U.S.PAT.NO: 5,977,337

Loosmore et al 1999 disclose isolated bacterial lactoferrin binding protein from *M.catarrhalis* strain 4223 in SEQ.ID.NO: 25. This recombinant protein comprises the disclosed

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peptide SEQ.ID.NO: 17 and is 100% identical to the claimed protein from position 100-113 (see the sequence alignment) The art discloses monoclonal antibodies or mono-specific antisera (antibodies) raised against the lactoferrin receptor protein produced (column 2, lines 30-35) and are useful for the diagnosis of infection by Moraxella, the specific detection of Moraxella (in, for example, in vitro and in vivo assays) and for the treatment of diseases caused by Moraxella . The art discloses said protein specifically binds to human lactoferrin (column 1, line 65) and is structurally identical to the claimed peptide, SEQ.ID.NO: 17 and therefore, antibodies to this peptide bind to plurality of lactoferrin binding proteins. In the absence of evidence to the contrary the claimed transferring binding peptide and the disclosed lactoferrin binding peptide appears to be the same as both contain 100% identical peptide. The art discloses vaccine composition comprising said lactoferrin-binding protein against gram-negative bacteria including *M.catarrhalis*, *N.meningitidis* and *Haemophilus influenzae* (see column 9, lines 24-44).

Remarks

12. No claims are allowed

Conclusion

13. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A

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message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Padma Baskar Ph.D.



LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINEE
TECHNOLOGY CENTER 1600

ALIGNMENTS

RESULT 1
US-08-613-009A-10
Sequence 10, Application US/08613.009A
; Patent No. 6090516
GENERAL INFORMATION:
APPLICANT: Myers, Lisa E
APPLICANT: Schryvers, Anthony B
APPLICANT: Harkness, Robin E
APPLICANT: Loosmore, Sheena M.
APPLICANT: Du, Run-Pan
APPLICANT: Yang, Yan-Ping
APPLICANT: Klein, Michel H
TITLE OF INVENTION: Transferrin Receptor Genes of Moraxella
NUMBER OF SEQUENCES: 31
REFERENCE/DOCKET NUMBER: 1038-544
ADDRESSEE: Sim & McBurney
STREET: 6th Floor, 330 University Avenue
CITY: Toronto
STATE: Ontario
COUNTRY: Canada
ZIP: MSG 1R7
COMPUTER READABLE FORM:
MEDIUM TYPE: Floppy disk
COMPUTER: IBM PC compatible
OPERATING SYSTEM: PC-DOS/MS-DOS
SOFTWARE: PatentIn Release #1.0, Version #1.30
CURRENT APPLICATION DATA:
APPLICATION NUMBER: US/08/613.009A
FILING DATE: 08-MAR-1996
CLASSIFICATION: 435
ATTORNEY/AGENT INFORMATION:
NAME: Stewart, Michael I
REGISTRATION NUMBER: 24973
REFERENCE/DOCKET NUMBER: 1038-542
TELECOMMUNICATION INFORMATION:
TELEPHONE: (416) 595-1155
TELEFAX: (416) 595-1163
INFORMATION FOR SEQ ID NO: 10
SEQUENCE CHARACTERISTICS:
LENGTH: 682 amino acids
TYPE: amino acid
STRANDEDNESS: single
TOPOLOGY: linear
US-08-613-009A-10

Query Match Score 74; DB 2; Length 682;
Best Local Similarity 100.0%; Pred. No. 1.9e-05;
Matches 14; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

RESULT 2
US-08-778-570B-12
Sequence 12, Application US/08778570B
; Patent No. 6417096
GENERAL INFORMATION:
APPLICANT: Myers, Lisa E
APPLICANT: Schryvers, Anthony B
APPLICANT: Harkness, Robin E
APPLICANT: Loosmore, Sheena M.
APPLICANT: Du, Run-Pan
APPLICANT: Yang, Yan-Ping
APPLICANT: Klein, Michel H
TITLE OF INVENTION: Transferrin Receptor Genes of Moraxella
NUMBER OF SEQUENCES: 43
REFERENCE/DOCKET NUMBER: 1038-544
TELECOMMUNICATION INFORMATION:
TELEPHONE: (416) 595-1155
TELEFAX: (416) 595-1163
INFORMATION FOR SEQ ID NO: 10
SEQUENCE CHARACTERISTICS:
LENGTH: 682 amino acids
TYPE: amino acid
STRANDEDNESS: single
TOPOLOGY: linear
US-08-778-570B-12

Query Match Score 74; DB 2; Length 682;
Best Local Similarity 100.0%; Pred. No. 1.9e-05;
Matches 14; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

RESULT 3
US-08-059-584-12
Sequence 12, Application US/09059584
; Patent No. 6440701
GENERAL INFORMATION:
APPLICANT: Myers, Lisa E
APPLICANT: Schryvers, Anthony B
APPLICANT: Harkness, Robin E
APPLICANT: Loosmore, Sheena M.
APPLICANT: Du, Run-Pan
APPLICANT: Yang, Yan-Ping
APPLICANT: Klein, Michel H
TITLE OF INVENTION: Transferrin Receptor Genes of Moraxella
NUMBER OF SEQUENCES: 60
REFERENCE/DOCKET NUMBER: 1038-542
TELECOMMUNICATION INFORMATION:
TELEPHONE: (416) 595-1155
TELEFAX: (416) 595-1163
INFORMATION FOR SEQ ID NO: 10
SEQUENCE CHARACTERISTICS:
LENGTH: 682 amino acids
TYPE: amino acid
STRANDEDNESS: single
TOPOLOGY: linear
US-08-059-584-12

Query Match Score 74; DB 2; Length 682;
Best Local Similarity 100.0%; Pred. No. 1.9e-05;
Matches 14; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

RESULT 4
US-08-778-570B-12
Sequence 12, Application US/08778570B
; Patent No. 6417096
GENERAL INFORMATION:
APPLICANT: Myers, Lisa E
APPLICANT: Schryvers, Anthony B
APPLICANT: Harkness, Robin E
APPLICANT: Loosmore, Sheena M.
APPLICANT: Du, Run-Pan
APPLICANT: Yang, Yan-Ping
APPLICANT: Klein, Michel H
TITLE OF INVENTION: Transferrin Receptor Genes of Moraxella
NUMBER OF SEQUENCES: 43

CLASSIFICATION:
 NAME: Stewart, Michael I
 REGISTRATION NUMBER: 24973
 TELECOMMUNICATION INFORMATION:
 TELEPHONE: (416) 595-1155
 TELEX/FAX: (416) 595-1163
 INFORMATION FOR SEQ ID NO: 12:
 SEQUENCE CHARACTERISTICS:
 LENGTH: 682 amino acids
 TYPE: amino acid
 STRANDEDNESS: single
 TOPOLOGY: linear
 US-09-059-584-12

Query Match Similarity 100.0%; Score 74; DB 2; Length 682;
 Best Local Similarity 100.0%; Pred. No. 1.9e-05;
 Matches 14; Conservative 0; Mismatches 0; Indels 0; Gaps 0;
 CORRESPONDENCE ADDRESS:
 Qy 1 MGYGMALSKINLNH 14
 Db 80 MGYGMALSKINLNH 93

RESULT 4
 US-08-867-941-25
 Sequence 25 Application US/08867941
 Patent No 5572337
 GENERAL INFORMATION:
 APPLICANT: Loosmore, Sheena M
 APPLICANT: Du, Run-Pan
 APPLICANT: Wang, Qijun
 APPLICANT: Yang, Yan-Ping
 APPLICANT: Klein, Michel H
 TITLE OF INVENTION: LACTOFERRIN RECEPTOR GENES OF MORAXELLA
 NUMBER OF SEQUENCES: 67
 CORRESPONDENCE ADDRESS:
 ADDRESSEE: Sim & McBurney
 STREET: 6th Floor, 330 University Avenue
 CITY: Toronto
 STATE: Ontario
 COUNTRY: Canada
 ZIP: MSG 1R7

COMPUTER READABLE FORM:
 MEDIUM TYPE: Floppy disk
 COMPUTER: IBM PC compatible
 OPERATING SYSTEM: PC-DOS/MS-DOS
 SOFTWARE: Patent In Release #1.0, Version #1.30
 CURRENT APPLICATION DATA:
 APPLICATION NUMBER: US/08/613,009A
 FILING DATE: 08-MAR-1996
 CLASSIFICATION: 435
 ATTORNEY/AGENT INFORMATION:
 NAME: Stewart, Michael I
 REGISTRATION NUMBER: 24973
 PREFERENCE/DOCKET NUMBER: 1038-542
 TELECOMMUNICATION INFORMATION:
 TELEPHONE: (416) 595-1155
 TELEFAX: (416) 595-1163
 INFORMATION FOR SEQ ID NO: 9:
 SEQUENCE CHARACTERISTICS:
 LENGTH: 702 amino acids
 TYPE: amino acid
 STRANDEDNESS: single
 TOPOLOGY: linear
 US-08-613-009A-9

Query Match Similarity 100.0%; Score 74; DB 2; Length 702;
 Best Local Similarity 100.0%; Pred. No. 2e-05;
 Matches 14; Conservative 0; Mismatches 0; Indels 0; Gaps 0;
 CORRESPONDENCE ADDRESS:
 Qy 1 MGYGMALSKINLNH 14
 Db 100 MGYGMALSKINLNH 113

RESULT 6
 US-03-074-658-25
 Sequence 25 Application US/09074658
 Patent No. 6184371
 GENERAL INFORMATION:
 APPLICANT: Loosmore, Sheena M
 APPLICANT: Run-Pan Du
 APPLICANT: Qijun Wang
 APPLICANT: Yang, Yan-Ping
 APPLICANT: Klein, Michel H
 TITLE OF INVENTION: LACTOFERRIN RECEPTOR GENES OF MORAXELLA
 NUMBER OF SEQUENCES: 78
 CORRESPONDENCE ADDRESS:
 ADDRESS: Sim & McBurney
 STREET: 6th Floor, 330 University Avenue
 Query Match Similarity 100.0%; Score 74; DB 1; Length 702;
 Best Local Similarity 100.0%; Pred. No. 2e-05;
 Matches 14; Conservative 0; Mismatches 0; Indels 0; Gaps 0;
 CORRESPONDENCE ADDRESS:
 Qy 1 MGYGMALSKINLNH 14